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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,483	03/19/2001	Yoshinobu Hanyu	P20757	8955

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EXAMINER	
SISSON, BRADLEY L	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/810,483	HANYU ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 33-54 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 33-54 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Prosecution Reopened

1. Applicant is advised that the Notice of Allowance mailed 11 June 2003 is vacated. If the issue fee has already been paid, applicant may request a refund or request that the fee be credited to a deposit account. However, applicant may wait until the application is either found allowable or held abandoned. If allowed, upon receipt of a new Notice of Allowance, applicant may request that the previously submitted issue fee be applied. If abandoned, applicant may request refund or credit to a specified Deposit Account.

Claim Objections

2. A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim.

3. A claim that depends from a dependent claim should not be separated by any claim, which does not also depend from said dependent claim. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 33-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

> To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Vas-Cath, 935 F.3d at 1563; see also Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); In re Gosteli, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572.

6. For convenience, claims 33-36, the only independent claims currently pending and under consideration, are reproduced below.

33. A powder containing a physiologically active peptide, wherein the powder comprises particles which particles comprise a physiologically active peptide and mannitol in a weight proportion of from 1:1 to 1:50, the particles further comprising per one part by weight of the physiologically active peptide at least one of a nonionic surfactant in an amount of 0.05-3 parts by weight, hydrogenated lecithin, and a binder selected from the group of polyvinylpyrrolidone, polyvinylalcohol, a water-soluble, nonionic, cellulose derivative, and mixtures thereof, in an amount of 0.05-6 parts by weight.

34. A powder containing a physiologically active peptide, wherein the powder comprises particles which particles comprise a physiologically active peptide and mannitol in a weight proportion of from 1:1 to 1:50, the particles further comprising per one part by weight of the physiologically active peptide a nonionic surfactant in an amount of from 0.05 to 3 parts by weight.

35. A powder containing a physiologically active peptide, wherein the powder comprises particles which particles comprise a physiologically active peptide and mannitol in a weight proportion of from 1:1 to 1:50, the particles further comprising per one part by weight of the physiologically active peptide a nonionic, organic, water-soluble binder in an amount of from 0.05 to 6 parts by weight.

36. A powder containing a physiologically active peptide, wherein the powder comprises particles which particles comprise a physiologically active peptide and mannitol in a weight proportion of from 1:1 to 1:50, the particles further comprising hydrogenated lecithin.

7. For purposes of examination, the claims have been interpreted as encompassing virtually any and every proteinaceous pharmaceutical, both known and unknown, and without regard to

condition(s) to be treated, whether or not the intended recipient is human or non-human. A review of the specification, however, fails to find an adequate written disclosure of the immense genus of proteins the claimed powders are to comprise.

8. Claims 46-48 limit the "physiologically active peptide" to where it "comprises human insulin." The specification does not provide a definition of what constitutes "human" as compared to non-human insulin, regardless of it being physiologically active or not. Accordingly, one would not be able to differentiate "human insulin" from any other insulin.

9. Similarly, claims 49-51 require the "physiologically active peptide" to comprise "human growth hormone." The specification does not provide an adequate written description of the structure and function of this peptide. Additionally, the specification does not provide an adequate written description of what makes the growth hormone "human" as compared to any other growth hormone.

10. In accordance with claims 43-51, the "peptide" is to "comprise" an unlimited amount of proteins. Such combinations have, for purposes of examination, been construed as encompassing chimeric proteins. As seen in claim 43, for example, the peptide is to "comprise growth hormones...[and] somatostatin derivatives." The specification does not provide an adequate written description of any growth hormone, much less chimeric forms of same. Similarly, the specification does not provide an adequate written description of "derivatives" of somatostatin. Accordingly, one would not be ale to identify what applicant considers to be a derivative encompassed by the claim from all other molecules, including chimeras. Additionally the specification fails to reasonably suggest that applicant was in possession of the crude peptides, much less a formulation of the peptides in the claimed powder.

11. While the specification does provide a listing of potential peptides that could be included in such a powder, the specification fails to teach in such full, clear, and concise language so as to reasonably suggest that applicant had possession of the broad genus of peptide-containing powders at the time of filing. The specification has been found to provide a description of a powder that comprises but a single peptide, "r-hGH." Attention is directed to the decision in *In re Shokal*, 113 USPQ 283 (CCPA 1957) wherein is stated:

> It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. In re Soll, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; In re Wahlforss et al., 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.
>
> ***
>
> We are of the opinion that a genus containing such a large number of species cannot properly be identified by the mere recitation or reduction to practice of four or five of them. As was pointed out by the examiner, four species might be held to support a genus, if such genus is disclosed in clear language; but where those species must be relied on not only to illustrate the genus but to define what it is, the situation is otherwise.

12. It appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

Accordingly, the specification fails to reasonably suggest that applicant had possession of the full genus of powders encompassed by the claims.

13. For the above reasons, and in the absence of convincing evidence to the contrary, claims 33-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

14. Claims 33-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of

> the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

15. As presented above, the specification does not reasonably suggest that applicant was in possession of the invention at the time of filing. It is well settled that one cannot enable that which they do not yet possess. Accordingly, the same deficient specification cannot and does not enable the making and use of these as yet unrealized and non-described peptide-containing powders.

16. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
>
> *****
>
> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.
> "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385,

> 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

17. For the above reasons, and in the absence of convincing evidence to the contrary, claims 33-54 are 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 31-35, 37-39, 41-45, 52, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,839,443 (Rose et al.), US Patent 5,607,915 (Patton), and US Patent 6,455,053 B1 (Okada et al.).

22. Rose et al., columns 5 and 6, disclose pharmaceuticals that comprise any of a wide variety of components, including a physiologically active peptide, Pluronic F68 (column 5, lines 31-32; applicant's non-ionic surfactant; page 19 of specification), mannitol (column 5, line 36), and a water-soluble, nonionic, organic binder such as polyvinylpyrrolidone (column 6, line 34). As set forth at column 5, line 27, such preparations may be lyophilized, and can be used as powder for pulmonary, nasal or oral administration (column 5, line 57). Such a disclosure meets a limitation of claims 33-35, 41, 42, 52 and 53.

23. Rose et al., do not teach the size of the particles of the lyophilized physiologically active peptide composition, the peptides recited in claims 43-45, and the concentration of the various ingredients, including the physiologically active peptide and mannitol.

24. Patton, column 5, teaches powders that comprise lyophilized parathyroid hormone, that can be configured so as to be used as an inhaler, and that they particles of the powder range in size from about 0.5 μm to 5 μm. This meets a limitation of claims 37-40, 43-45, 52 and 53.

25. Patton, column 5, lists a plethora of ingredients that may be combined with the physiologically active peptide, including mannitol, at line 50.

26. Patton, column 6, teach the physiologically active peptide may be present at a range of from about 1% to about 25% by weight of the powder.

27. Patton does not teach the relative concentration of physiologically active peptide and mannitol.

28. Okada et al., columns 4-5, teach formulations of a powder that can comprise a physiologically active peptide, mannitol (column 5, line 9), polyvinylpyrrolidone (PVP; column 4, lines 63-64; applicant's "water-soluble, nonionic, organic binder"), as well as additional ingredients.

29. Okada et al., column 5, teach the saccharide (e.g., mannitol) may be present "in an amount of 40% by weight or more, and more preferably in an amount of 60% by weight or more in terms of the total solid content of the preparation." Such a showing meets the limitation that the "physiologically active peptide and mannitol be present in a weight proportion of from 1:1 to 1:50," which is a limitation of claims 33-36.

30. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modified the lyophilized physiologically active peptide composition of Rose et al., in accordance with the disclosures of Patton and Okada et al., as such would have resulted in a

powder that would have a size suitable for use in inhalation therapy, and would have also exhibited improved solubility.

31. While the prior art des not teach the specific concentrations of either water-soluble, nonionic, organic binder (e.g., PVP), or of the nonionic surfactant (e.g., Pluronic F68), such concentrations of formulation are considered to be the result of routine optimization and to not constitute a patentable difference over the prior art of record. It is well settled that routine optimization is not patentable, even if it results in significant improvements over the prior art. In support of this position, attention is directed to the decision in *In re Aller, Lacey, and Hall*, 105 USPQ 233 (CCPA 1955):

> Normally, it is to be expected that a change in temperature, or in concentration, or in both, would be an unpatentable modification. Under some circumstances, however, changes such as these may impart patentability to a process if the particular ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art. In re Dreyfus, 22 C.C.P.A. (Patents) 830, 73 F.2d 931, 24 USPQ 52; In re Waite et al., 35 C.C.P.A. (Patents) 1117, 168 F.2d 104, 77 USPQ 586. Such ranges are termed "critical" ranges, and the applicant has the burden of proving such criticality. In re Swenson et al., 30 C.C.P.A. (Patents) 809, 132 F.2d 1020, 56 USPQ 372; In re Scherl, 33 C.C.P.A. (Patents) 1193, 156 F.2d 72, 70 USPQ 204. However, even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. In re Sola, 22 C.C.P.A. (Patents) 1313, 77 F.2d 627, 25 USPQ 433; In re Normann et al., 32 C.C.P.A. (Patents) 1248, 150 F.2d 708, 66 USPQ 308; In re Irmscher, 32 C.C.P.A. (Patents) 1259, 150 F.2d 705, 66 USPQ 314. More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Swain et al., 33 C.C.P.A. (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D. C. 324, 135 F.2d 11, 57 USPQ 136. (Emphasis added)

32. For the above reasons, and in the absence of convincing evidence to the contrary, claims 31-35, 37-39, 41-45, 52, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over

US Patent 5,839,443 (Rose et al.), US Patent 5,607,915 (Patton), and US Patent 6,455,053 B1 (Okada et al.).

33. Claims 43-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,839,443 (Rose et al.), US Patent 5,607,915 (Patton), and US Patent 6,455,053 B1 (Okada et al.) as applied to claims 31-35, 37-39, 41-45, 52, and 53 above, and further in view of US Patent 5,334,162 (Harris) and US Patent 5,997,848 (Patton et al.).

34. See above for the basis of the rejection as it relates to the disclosures of Rose et al., Patton, and Okada et al.

35. Neither Rose et al., Patton, nor Okada et al., teach the physiologically active peptide being insulin or human growth hormone.

36. Harris, column 1, lines 42-44, teaches explicitly of lyophilizing physiologically active peptides such as insulin and human growth hormone. This meets a limitation of claims 43-51.

37. Patton et al., teaches preparing lyophilized insulin in a powder suitable for inhalation, and that the powder has a particle size of less than 10 μm.

38. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have adapted the powder of Rose et al., Patton and Okada et al., such that it comprised either insulin or human growth hormone as Harris and Patton et al., teach of their medical significance and desirability of having same in a lyophilized form. In view of such explicit teachings, the ordinary artisan would have been both amply motivated and would have had a mot reasonable expectation of success. Therefore, and in the absence of convincing evidence to the contrary, claims 43-51 are rejected under 35 U.S.C. 103(a) as being unpatentable

over US Patent 5,839,443 (Rose et al.), US Patent 5,607,915 (Patton), and US Patent 6,455,053 B1 (Okada et al.) as applied to claims 31-35, 37-39, 41-45, 52, and 53 above, and further in view of US Patent 5,334,162 (Harris) and US Patent 5,997,848 (Patton et al.).

39. Claims 36 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,839,443 (Rose et al.), US Patent 5,607,915 (Patton), and US Patent 6,455,053 B1 (Okada et al.) as applied to claims 31-35, 37-39, 41-45, 52, and 53 above, and further in view of US Patent 4,963,367 (Ecanow) and US Patent 6,117,434 (Oyama et al.).

40. Neither Rose et al., Patton, nor Okada et al., teach including hydrogenated lecithin in the powder.

41. Ecanow, abstract, teaches preparing drugs for use in inhalation. Column 13 teaches including soy lecithin along with peptide and/or peptide compositions. Column 14 teaches including polysorbates (applicant's non-ionic surfactant).

42. Ecanow, column 13, teach that the composition may include physiologically active peptides such as human growth hormone and Factor IX.

43. Ecanow, column 17, teaches the lecithin used in the composition can be that subjected to hydrolysis.

44. Ecanow does not teach explicitly of using hydrogenated lecithin.

45. Oyama et al., column 2, teaches using lecithin, "including even hydrogenated lecithin" as it has enhanced solubility.

46. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated hydrogenated lecithin into the powder of Rose et al., Patton and

Okada et al., as such would have allowed for enhanced solubility and increased stability. In view of the detailed teachings, and use of lecithins in a wide variety of compositions, the ordinary artisan would have been amply motivated and would have also had a most reasonable expectation of success. For the above reasons, and in the absence of convincing evidence to the contrary, claims 36 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,839,443 (Rose et al.), US Patent 5,607,915 (Patton), and US Patent 6,455,053 B1 (Okada et al.) as applied to claims 31-35, 37-39, 41-45, 52, and 53 above, and further in view of US Patent 4,963,367 (Ecanow) and US Patent 6,117,434 (Oyama et al.).

Conclusion

47. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

48. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

49. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
15 March 2005